REMARKS

Reconsideration of this application is requested. Claims 16-33 are active in the application subsequent to entry of this amendment. On July 30, 2001 a three month extension of time was purchased and a Continued Prosecution Application filed.

This response replies to the issues raised in the Official Action of January 30, 2001, paper no. 7.

The claims have been amended in order to more particularly point out and distinctly claim that which applicants regard as their invention. In overview, new claims 16-23 and 27-33 correspond generally to original claims 1-8, 3 and 9-15, respectively.

Independent claims 16, 21 and 22 have replaced previous claims 1, 7 and 8; the use of sodium carbonate and potassium carbonate is no longer included in these claims. New claims 24-26 have been added directed to preferred aspects of the disclosure. As described in applicants' specification, typically components (A) and (B) are mixed uniformly with each other and this is described at pages 14 and 15 of the application and forms the basis for new claim 24. In the preferred aspect, component (A) and a portion of component (B) are mixed together, then a further amount of component (B) is added and it may take the form of being added to the core or coating applied to it as an outer layer to the core, again as described at pages 14 and 15 of the specification which supports new claim 25.

New claim 25 is directed to a preferred aspect of the invention as illustrated in working example 27. In this embodiment, component (A) is mixed with a portion of component (B) to form granules, then a small amount of component (B) is added to make tablets. In this embodiment, the first-formed granules and the later amount of component (B) are mixed thoroughly together such that a portion of component (B) exists in the granules and another portion of component (B) exists separately outside the granules as

defined in claim 25. In another embodiment of the invention as illustrated in Examples 19 and 20 is featured in claim 26, components (A) and (B) are well mixed together to form a core then provided with a coating layer of a further amount of component (B) which acts as an intermediate layer for further coating or coatings. In addition to these amendments various adjustments and refinements were made to the claims for purposes of clarity and form of presentation.

The issues raised in the outstanding Official Action all relate to the citation and application of prior art to the claims as originally filed. To the extent that the examiner's concerns may extend to the new claims presented above, the rejections are all traversed. Applicants' claims are novel over the references cited as they do not disclose the materials specified in component (B) of the claimed compositions.

Considering first published PCT application WO 97/25066 to Depui et al, the examiner draws attention to page 15, lines 1-15 of the description. Here applicants are describing mixing a proton pump inhibitor mixed with "an alkaline, pharmaceutically acceptable substance," typically, as illustrated in the mentioned passage, they are "substances normally used in antacid preparations." By contrast, applicants provide for the use of sodium hydroxide or potassium hydroxide which are base and not typically used in antacid preparations.

The formulations of the present invention exhibit unexpectedly improved stability properties and compatibility with the proton pump inhibitor active material. This is illustrated throughout the specification of this application and in particular and the data given in Tables 1-3, pages 16-17 of the specification. Compatibility and stability date are reported even at temperatures and humidities as high as 40°C at 75% humidity. This is to be contrasted with materials such as aluminum hydroxide (specifically mentioned in Depui et al). Particularly impressive results are obtained using crospovidone as shown in Examples 10-12. Formulations for these examples are given on page 5 of the specification, data for which are given in Table 5, page 18 of the specification, assessed

in terms of HPLC and subsequent prevention of color change. Applicants have found in particular that fine powders of crospovidone provide better improvements as compared to other formulations. When component (B) is crospovidone, it may be in the form of fine powder or well mixed with component (A) which applicants have found serves to stabilize the shape of the tablet. The cited Depui et al reference does not describe but the advantages achieved by applicants in their claim formulations.

U.S. Patent No. 6,030,988 to Gillis et al describes various oral dosage forms and mentions as disintegrants materials such as cross-linked povidone at column 6, lines 56-60. Applicants acknowledge that this information exists, however, there is nothing in the disclosure of this document to suggest the effects achieved by crospovidone in terms of stability of a proton pump inhibitor.

The inventive pharmaceutical preparations and formulations defined in previous claims 14 and 15, now new claims 32 and 33, are characterized by a moisture-resistant coating which enables the tablet to maintain its form and prevents it from becoming deformed such as when the core swells. This enables a controlled constant dose of the drug to be administered.

Also cited is U.S. Patent No. 5,708,017 to Dave et al which relates to pharmaceutical pastes to be administered to horses. In discussing the background of their disclosure, Dave et al referred to proton pump inhibitors as being "highly acid labile and hence oral formulations are intera-coated." Applicants acknowledge the comments provided by the Dave et al reference in terms of background of their formulations for treating horses, however, it merely illustrates the problems relating to proton pump inhibitors which, as a group, are generally unstable to an acid environment hence the use of an intera-coating. From the above discussion, it will be apparent that applicants do not agree with the citation and application of the primary reference to Depui et al much less the ancillary descriptions provided Gillis et al citation. Applicants' formulations provide unexpectedly superior properties to various products described in the prior art, properties

and advantages no where reasonably expected from the disclosures of the documents cited. Moreover, there appears to be no common ground or reason to combine the documents in that the contents of one do not necessarily lead to the content of the other.

Reconsideration of this application and favorable action are solicited.

Respectfully submitted,

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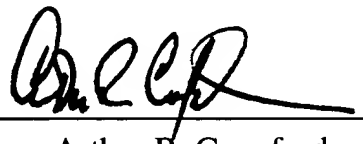
By: 

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